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SANDIA NATIONAL LABORATORIES
QUALITY ASSURANCE PROGRAM
for the
OFFICE of CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QAP 20-1

TEST PLANS

REVISION 1

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CHANGE HISTORY

Revision	Description	Effective Date
0	This is the initial version of this document.	05/13/2004
1	Administrative changes resulting from Audit OQA-FS-04-07	05/20/2004

TABLE OF CONTENTS

1.0 Purpose and Scope

This procedure prescribes the requirements for preparing, approving, revising, and implementing test plans. Plans include Technical Work Plans (TWPS) and test plans governing test and analysis activities and are referred to as Test Plans (TPs) for the Office of Science and Technology and International (OSTI) Science and Technology activities, data collection (i.e., laboratory or field), routine calculations, or analysis may be conducted by the Sandia National Laboratories (SNL) project staff or by other project suppliers (i.e., LANL, PNNL etc…). The use of the experimental information gathered or of the analysis results are of varying importance. The controls established by the planning activity should be commensurate with the intended use of the activity.

This procedure applies to the planning and documentation of:

- Field and laboratory experiments,
- Testing and experimental activities that produce data.
- Analysis of that data

Controls for routine calculations supporting technical activities are described in QAP 20-2 Scientific Notebooks and Routine Calculations. Software development and use are covered in the QAP 19-1 Software Management.

The scope of this procedure addresses the requirements for preparation and use of TWPs and TPs, and applies to staff, suppliers, and others who plan, prepare, conduct, and oversee scientific investigations for the Office of Civilian Radioactive Waste Management (OCRWM) and work to the OSTI Quality Assurance (QA) Program.

Acronyms and definitions for terms used in this procedure may be found in the OSTI Glossary.

2.0 Implementation Actions

2.1 General Requirements

2.1.1 Technical Work Plans (TWPs)

TWPs are written to provide high-level information needed to release funding for the activity, subdivide the activity into tasks and assign responsible individuals and organizations.

2.1.2 Test Plans (TPs)

TPs are written to ensure that a scientific activity (or activities) and the analysis of that activity data is accomplished under appropriate controlled conditions. The author of a TP shall either be the principal investigator (PI) or be selected by the PI or the Manager Responsible for the work activity. TPs shall be approved prior to initiation of work, and describe the scientific activity in sufficient detail to allow the test or experiment to be conducted.

The PI shall ensure that the scientific activity is planned, documented, reviewed, and approved through review and approval of the TP. The content requirements for TPs are listed in Appendices A and B.

Note: Use of National Standards. When reference standards are used without modification, the TP shall document the standard by reference only. If deviations from test standards or the establishment of specially prepared test procedures is deemed appropriate (e.g., no nationally recognized test standards exist) the modified or new test procedures shall be documented in sufficient detail to be repeatable, and shall be justified, evaluated, and approved by the cognizant technical organization. The differences shall either be defined in the TP, or documented as a Experimental Implementing Procedure (EIP), reference QAP 5-1 (Implementing Procedures), or documented by using a Scientific Notebook (SN), reference QAP 20-2 (Scientific Notebooks), whichever is appropriate.

2.2 Document Format

2.2.1 Cover Page: The TP shall include the following and be similar to the Cover page for Procedures shown in Appendix A, QAP 5-1:

- "Test Plan"
- TP number assigned by Document Control
- TP Title
- Author(s) Name(s), Organization(s)
- Revision Number
- Effective Date: _____

Note: Both the TP number and the effective date are assigned by the OSTI Document Control Staff. The first issue of a TP is “Revision 0”.

2.2.2 Document Control Header

Each page of a TP shall bear the following document control header, located in the upper right-hand side of the page:

TP (number)
Revision (number)
Page (number) of (total number)

2.2.3 Content

The required content of the TP is described in Appendix A. for laboratory and field activities and for analysis activities. When both activities are covered by the same TP the experimental work shall be described first and then the analysis. Data records are described in the QAP for Technical Reporting and Data Records.

2.3 Test Plan Review and Approval Process

The author shall:

- Obtain a TP control number from the OSTI Document Control Staff,
- Prepare the text of the TP in accordance with Appendix A, and
- Forward the draft TP to the assigned reviewers.

Reviewers shall:

- Review the TP according to QAP 6-1 (Document Review Process).
- Verify that the TP meets the requirements of this procedure, including Appendices A and B.

The following are the minimum required approval signatures:

- Technical reviewer
- QA reviewer
- Responsible Manager

The PI may add additional reviewers as necessary, for example:

- Customer and/or contractor required reviews
- Safety reviews (lab or field)

Reviewers and authors shall sign the TP or revision. The required signatures and applicable Document Review and Comment forms (DRC) indicate that the TP or revision was reviewed, review comments were satisfactorily resolved and incorporated, and the TP or revision is approved for use, subject to its effective date.

2.4 Changes to Test Plans

The author shall ensure revisions to the Test Plan are clearly indicated with vertical change bars in the margin of the revised plan (Note: change bars will indicate changes for the current revision only). Changes to TPs shall be made in accordance with QAP 6-1.

2.5 Issuance and Control

Controlled documents shall be issued in accordance with QAP 6-2 (Document Control Process).

2.6 Test Plan Implementation

The Sandia PI or designee shall:

- Oversee implementation of the TP.
- Revise the TP, as necessary.
- Oversee preparation of TP Data Record.

A TP Data Record shall provide sufficient documentation so a qualified technical person independent of the work could reconstruct the work and reproduce the results of the corresponding TP. The data shall be identifiable and traceable to the test or source and controlled to avoid loss and ensure retrievability. Data records and analysis activities need to be included in the planning activity.

3.0 Records

The following QA records, generated through implementation of this procedure, shall be prepared and submitted to OCRWM and a copy to the SNL Records Center in accordance with QAP 17-1 (Records).

QA Record

- The final, approved new/revised TP
- DRC forms (QAP 6-1-1), if required
- Copies of Markups

4.0 Appendices

Appendix A: Experimental Test Plan Content and Format
Appendix B: Analytical Test Plan Content and Format

Appendix A
Experimental Test Plan Content and Format

For Field and Laboratory Activities

Experimental test plans shall include the following, unless the nature of the work does not involve the item or concept:

- **Title and Header Information** - See format in Section 2.2.
- **Approvals** - Provide the name, title, and dated signatures of persons approving the TP, including the author and reviewers (technical, QA and management)**.**
- **Table of Contents** - Provide an outline of the TP contents and the corresponding pages at which the sections start.
- **Revision History** - Describe the purpose and content of each revision made.
- **Purpose and Scope** – Describe the purpose and scope of the scientific activity (hypothesis or hypotheses to be tested), and the intended use of the data.
- **Experimental Process Description** – Describe the primary tasks and the conduct of the scientific investigation activity, addressing the following (note: if specifics are not known, describe how they will be documented during the scientific investigation activity):

  Planning Overall Strategy and Process
  - Critical variables to be measured and controlled
  - Coordination with organizations providing inputs or using the results
  - Procedures to be used/developed
  - Identification of prerequisites, special controls (including controls to prevent tampering of data during acquisition and analysis), specific environmental conditions, processes, or skills.
  - Known sources of error and uncertainty including any uncertainty about the quality of input data
  - Compatibility of data processing with any conceptual/mathematical models used at each applicable stage
  - Specify documents to be maintained as QA records (e.g., scientific notebooks)

  Sample Control
  - Sample labeling/identification method to be used (e.g., as described/recorded in scientific notebook)
  - Sample handling/nonconforming requirements - reference QAP 13-1 (Samples, Chemical Standards, and Chain-of-Custody)
  - Sample storage and/or environmental controls
  - Sample disposal

  Data Quality Control
  - Measuring and Test Equipment (M&TE) - reference QAP 12-1 (Measuring and Test Equipment)
    - Calibration requirements
    - Use of M&TE, standards, and other tools
  - Data Acquisition System (DAS)

- For the intended use, identify required periodic in-use manual or automatic self-check routines (e.g., visual data inspection, established alarm interval limits, calibrated source)
- For commercial software not modified, document the name, version and the hardware for which it is used
- For developed or modified stand alone software (i.e., software which can be operated and verified independent of the hardware system), refer to QAP 19-1, Software Development and Use.
- Methods for justification, evaluation, approval, and documentation of any deviations from test standards or of establishment of specially prepared test procedures (e.g., when no nationally recognized test standards exist)
- Controls/reference sample use (e.g., use of replicates, spikes, split samples, control charts, blanks, reagent checks, etc., as appropriate)
- Control and characterization of test media (e.g., fluids)

Data Identification and Use

- Method(s) of recording data (e.g., scientific notebook, log books, data sheets)
- Data transfer and reduction controls
- Control of erroneous or inadequate data (includes identification, segregation, and disposition)
- Data conversion controls

- **Training –** Identify special training requirements, if applicable (reference QAP 2-1, Qualification and Training).
- **Health and Safety** – Describe any unique health and safety hazards associated with this work, and describe specific requirements and procedures to mitigate impact.
- **Permitting/Licensing** – Discuss special permitting or licensing requirements, which may be required to conduct the scientific activity (e.g., state permit to drill wells).

- **References** – List documents referenced in the TP in sufficient detail (e.g., author, journal name, publish date) to allow copies to be obtained by the acronyms and definitions for terms used in this procedure may be found in the OSTI Glossary or may be included in the document text.

Appendix B
Analytical Test Plan Content and Format

Analytical test plans shall include the following:

- **Cover page**
  - Title of Analysis
  - Effective date (assigned by Document Control)
  - Author (name, title, organization, signature, date)
  - Technical, QA and Management Reviewers (name, title, organization, signature, date)

- **Document Control Header**
  - To be included on the upper right-hand side of each page.
  - Analysis plan number (obtained from Document Control)
  - Revision Number
  - Page (number) of (total number)

- **Content Requirements** – The following shall be included, unless the nature of the work does not involve the item/concept.

1. **Introduction and Objectives.** A description of the scope of the analysis, the objectives to be achieved or hypotheses to be tested, and the initial assumptions:
   - discussion of the conditions, scenarios and general purpose of the analysis
   - description of assumptions relating to the implementation of any conceptual models
   - identification of potential sources of error and uncertainty and how they will be controlled
   - type of analysis to be performed (i.e., compliance decision or programmatic decision)

2. **Approach.** A description of the analytical approach, including a discussion of the computer codes and parameter input to be used in the analyses.

3. **Software List.** List software expected to be used.

4. **Tasks.** A listing of the primary tasks and how they will be documented, the identity of the individuals who will perform the tasks, task deliverables and expected completion date.

5. **Special Considerations.** The identification of prerequisites, special controls, processes, skills and certification requirements

Applicable Procedures. The identification of any applicable controlling documents, such as program procedures shall be included.